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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,841	03/01/2002	Martin Caldwell	1890-0020	1503

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EXAMINER

THALER, MICHAEL H

ART UNIT PAPER NUMBER

3731

DATE MAILED: 05/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/936,841

Applicant(s)

CALDWELL ET AL.

Examiner

Michael Thaler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 7-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 7-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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The disclosure is objected to because of the following informalities: Reference numerals 2 and 10 are absent from the drawings. Appropriate correction is required.

Claims 1-4, 7-10, 13 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claim 1, line 9, "connectable" should be "connected" since there is no indication in the original disclosure that the sleeve is removable from the body cavity engagement means and the fixing means.

Claims 9, 11, 12, 14, 15, 17 and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is unclear from the specification and drawings how the external proximal valve is structured and how it is connected to proximal ring 6. Since sleeve 4 is wrapped around proximal ring 6 as seen in figure 2, it is not seen how sleeve 4

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can extend proximally to form the external proximal valve. If a structure other than sleeve 4 forms the external proximal valve (which is not disclosed), then it is unclear how this structure is connected to proximal ring 6.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The valve defined in claim 3 has already be defined in claim 1 as the sealing means, resulting in a double recitation of the same part.

Claims 1-4 and 7-18 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bonadio (WO 95/22289). Bonadio discloses body cavity engagement means (the distal ring formed by arcuate bands 55, 55), fixing means including proximal ring 44, sleeve (the sleeve which passes within the incision) and sealing means 102. Pulling the proximal ring upwards would inherently cause the sleeve to apply outward pressure against the patient's body to retract the incision. Alternatively, it would have been obvious that pulling the proximal ring upwards would cause the sleeve to apply outward pressure against the patient's body to retract the incision since the portion of the sleeve within the incision would be forced upwards and radially outwards. As to claim 4,

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Bonadio discloses connector ring 42 as broadly claimed. As to claim 9, Bonadio discloses external proximal valve (e.g. 100). As to claim 11, rotating the proximal ring will inherently twist the sleeve and thereby shorten it. As to claims 13-15, Bonadio discloses elasticized filaments 55, 55. As to claims 16-18, Bonadio discloses tensioned member 55.

Claims 1-4 and 7-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crook (5,649,550) in view of Bonadio (WO 95/22289). Crook discloses body cavity engagement means (distal ring 20), fixing means including proximal ring 18, sleeve 12 wherein positioning the proximal ring retracts the sleeve to cause the sleeve to apply outward pressure against the patient's body to retract the incision (col. 4, lines 42-47). Crook fails to disclose sealing means. However, Bonadio teaches that sealing means (e.g. 100, 101 or 102) should be formed on the sleeve of an access port in order to insure that gas does not escape the patient. It would have been obvious to include a seal on the Crook device so that it too would have this advantage.

Applicant's arguments filed April 1, 2004 have been fully considered but they are not persuasive. As to the new matter rejection, although the original specification may not exclude

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the invention from including a removable sleeve, it still does not disclose this feature.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (703) 308-2981. The examiner can normally be reached Monday to Friday.

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The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

mht
5/14/04



MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731